

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. :	10/695,427	Confirmation No. :	4477
Applicant :	Geiss et al.		
Filed :	October 28, 2003		
TC/A.U. :	1614		
Examiner :	Spivak, Phylis G.		
Docket No. :	7390-X03-020		
Customer No. :	27317		

RESPONSE TO PAPER 20070616 HOLDING AMENDMENT NON-RESPONSIVE

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Examiner Spivak:

Responsive to the Office communication (PAPER 20070616) dated June 20, 2007; applicant respectfully traverses the holding by the Examiner that the amendment filed on April 13, 2007, together with a Declaration Under Rule 1.132 proving efficacy and an actual reduction to practice of the invention claimed in claims 19 to 25, responding to a non-final action dated November 15, 2006, was non-responsive because the claims 19 to 25 were directed to a non-elected invention.

Applicant strongly solicits that the holding be withdrawn because it is just plain wrong and not in compliance with the Statute and Regulations, and that the amendment and supporting Declaration be accepted as responsive to the non-Final action of November 15, 2006.

In support of the above, applicant noted the following:

1. The amendment filed on April 13, 2007 cancelled claims 1 to 18 (pending in the case) and submitted new claims 19 to 25 of which claims 19 and 20 were independent and claims 21 to 25 were dependent. Cancelled claims 1 to 18 included three independent claims: claim 1 directed to "Method for acceleration of a

physiological recovery process of a body of a user after a physical exertion . . .”; claim 11 directed to “A method for acceleration of a physiological recovery process of a body of a user after a physical and/or mental stressing . . .”; and claim 18 directed to “A method for acceleration of a physiological recovery process of a body of a user after a mental stressing . . .”. Claims 19 to 25 represented (i) a serious reduction in the number of claims, (ii) a serious limitation of the claims to physical stressing only (dropping any claim to mental stressing), (iii) a serious limitation of the claims by adding further limitations taken from the specification in order to more precisely particularly point out and distinctly claim the invention described in the specification, and (iv) to respond to the Examiner’s criticism of the claims 1 to 18 vis-à-vis Section 112 regarding possession of invention claimed, scope of claims and efficacy, see Office Action mailed November, 15, 2006, particularly pages 3 to 6.

2. A purported restriction requirement had been made in the 3rd action on this application, but was withdrawn after traversal. At the time of the non-Final action of November 15, 2006, there had not been any valid restriction requirement, no election of an invention, and no withdrawn claims to a non-elected invention in this application; all claims were being actively prosecuted.
3. A claim chart has been prepared for claim 19 showing that each limitation of claim 19 is fully supported by the specification, and the following quoted paragraphs of the specification show clearly and unambiguously the support for each and every limitation in the claim. Note particularly paragraphs [0008], [0016], [0024] and [0026] of the specification, which characterize the present invention.

Claim 19. (New)

**PARAGRAPH CITATIONS OF
 SPECIFICATION IN SUPPORT OF
 CLAIM LIMITATIONS**

A method of treating extreme physical stress in a human comprising the steps of	<p>SUMMARY OF THE INVENTION</p> <p>[0008] The present invention provides a method for treating a person under extreme stress, either physical or mental, with at least 50 mg of L-Theanine for purpose of acceleration of regeneration.</p> <p>[0016] It is to be noted that the present invention provides a method to</p>
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	<p>substantially accelerate the natural regeneration process after severe or extreme physical and / or mental stressing of a human.</p> <p>[0024] The investigation model is based on the production of physical stress by means of almost maximum bicycle ergometry as a method which is independent of surroundings, reproducible, reliable and exactly meterable individually according to a pre-test, and which triggers well-researched adaptation reactions.</p> <p>Investigation design and methods</p> <p>[0026] The bicycle ergometry is effected as a multi-stage test with increase up to near maximum functional capacity. The stage height and the maximum performance is determined in a pre-test, which proceeds starting from 50 watts with increase by 50 watts every 3 minutes up to physical exhaustion. The last stage lasting 3 minutes is the criterion for the actual test stress. It is reached there in 4 equal incremental stages each of 3 minutes and then as the fifth stage, 4 minutes are taken. (Variation possibilities: ramp stress, maximum steady state).</p>
<p>treating a human, exercised to near physical functional capacity and who is experiencing extreme physical stress as evidenced by raised serum prolactin levels in the human,</p>	<p>SUMMARY OF THE INVENTION</p> <p>[0008] The present invention provides a method for treating a person under extreme stress, either physical or mental, with at least 50 mg of L-Theanine for purpose of acceleration of regeneration.</p> <p>[0016] It is to be noted that the present invention provides a method to substantially accelerate the natural regeneration process after severe or extreme physical and / or mental stressing of a human.</p> <p>[0024] The investigation model is based on the production of physical stress by means of almost maximum bicycle ergometry as a method which is independent of surround-</p>

	<p>ings, reproducible, reliable and exactly meterable individually according to a pre-test, and which triggers well-researched adaptation reactions.</p> <p>Investigation design and methods</p> <p>[0026] The bicycle ergometry is effected as a multi-stage test with increase up to near maximum functional capacity. The stage height and the maximum performance is determined in a pre-test, which proceeds starting from 50 watts with increase by 50 watts every 3 minutes up to physical exhaustion. The last stage lasting 3 minutes is the criterion for the actual test stress. It is reached there in 4 equal incremental stages each of 3 minutes and then as the fifth stage, 4 minutes are taken. (Variation possibilities: ramp stress, maximum steady state).</p> <p>[0025] Measurement of the hypophyseen hormone prolactin in the blood serum, which after physical stress reacts like a stress hormone, plays a particular part in the selection of the hormonal parameters, since it is under the control of the central neurotransmitters dopamine (inhibits secretion) and serotonin (promotes release) and thus may reflect the central situation of these two systems. The concentrations of the catecholamines dopamine, noradrenalin and adrenalin in the blood plasma with their different origins (sympathetic ganglia, adrenal medulla) and their effects on circulation and metabolism are selected as further stress parameters from the peripheral ergotropic sympathetic system, and the serum level of the metabolism-stabilising and immune function-controlling adrenal cortex hormone cortisol. Measurement of serotonin in the blood serum may be used by way of supplement, even if the origin of the serotonin measured in the periphery cannot be assigned exactly. For longer observation periods, the rates of deposition of the degradation products of catecholamines and serotonin in the urine may also be informative.</p>
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by the human consuming at least 50 mg of L-theanine,	<p>[0027] The first measurement is effected immediately after the end of stress, the test drink is then administered and the recovery phase introduced in standardised manner (usually while lying in a separate peaceful darkened room). Further measurements are effected up to 2 hours after administration of the drink, wherein focus must be directed towards the known or to be foreseen uptake and distribution rate of the test substance into the brain.</p> <p>Results of the investigation on the effect of L-theanine-containing drinks</p> <p>[0028] Drinks with 0 and 50 and 200 mg of L-theanine tasting the same and looking identical were investigated in double-blind manner controlled by placebo under exactly the same conditions according to the above investigation model.</p> <p>[0029] Due to physical near maximum stress, there is in the EEG a rise in electrical performance in all frequency ranges and displacement in the spectral performance density to higher frequencies.</p>
and then resting the extremely physically stressed human for a period of 30 minutes,	<p>[0027] The first measurement is effected immediately after the end of stress, the test drink is then administered and the recovery phase introduced in standardised manner (usually while lying in a separate peaceful darkened room). Further measurements are effected up to 2 hours after administration of the drink, wherein focus must be directed towards the known or to be foreseen uptake and distribution rate of the test substance into the brain.</p> <p>[0040] Usually this regeneration process of the human brain after stressing takes between one and two hours. When a dose of at least 50 mg L-Theanine is administered after the stressing, the natural regeneration process is substantially accelerated and takes only about 30 minutes. This substantial acceleration of the natural</p>

	regeneration process after stressing is due to the acceleration of the physiological regeneration mechanisms by the L-Theanine.
during which time the peripheral controls of the human including the raised serum prolactin levels are reduced and are increasingly coupled to the human central nervous controls including neurotransmitters, dopamine, epinephrine, norepinephrine and serotonin, which are substantially unaffected,	<p>[0025] Measurement of the hypophyseal hormone prolactin in the blood serum, which after physical stress reacts like a stress hormone, plays a particular part in the selection of the hormonal parameters, since it is under the control of the central neurotransmitters dopamine (inhibits secretion) and serotonin (promotes release) and thus may reflect the central situation of these two systems. The concentrations of the catecholamines dopamine, noradrenalin and adrenalin in the blood plasma with their different origins (sympathetic ganglia, adrenal medulla) and their effects on circulation and metabolism are selected as further stress parameters from the peripheral ergotropic sympathetic system, and the serum level of the metabolism-stabilising and immune function-controlling adrenal cortex hormone cortisol. Measurement of serotonin in the blood serum may be used by way of supplement, even if the origin of the serotonin measured in the periphery cannot be assigned exactly. For longer observation periods, the rates of deposition of the degradation products of catecholamines and serotonin in the urine may also be informative.</p> <p>[0035] L-Theanine in the dose range 50 to 200 mg does not trigger quantitative and fundamental changes in physiological sequences of down-regulation after stress in the pharmacological sense, but acts to accelerate the processes of switching from stress to recovery, thus supports switching into the relaxation phase after stress in the sense of promoting regeneration. Due to the changed correlations and the effect on the prolactin level, analogously to results from animal tests known from the literature, it may be assumed that the mechanisms lie in the central</p>

	<p>neurotransmitter system and at the switch points between central electrical brain activity and the peripheral hormonal control and regulating system. The accelerated drop in activity in the rapid electrical frequency ranges in the areas of processing sensory stimuli and in the region of switching electrical performances in the cerebral cortex to hormonal regulation proposals, the shift to other stress hormones but while retaining the hormonal reactivity, is presumably particularly relaxation-promoting.</p>
<p>thereby accelerating recovery of the human from extreme physical stress to complete regeneration.</p>	<p>[0017] Usually the duration which is required for full regeneration after stressing is about one to two hours. In accordance with the invention, a dose of at least 50 mg L-Theanine is administered after the stressing by the person ingesting or drinking a food containing the L-Theanine. This way the regeneration process is substantially accelerated. For example the natural regeneration process can be shortened to about 30 minutes.</p> <p>[0040] Usually this regeneration process of the human brain after stressing takes between one and two hours. When a dose of at least 50 mg L-Theanine is administered after the stressing, the natural regeneration process is substantially accelerated and takes only about 30 minutes. This substantial acceleration of the natural regeneration process after stressing is due to the acceleration of the physiological regeneration mechanisms by the L-Theanine.</p>

4. Independent claim 20 is reproduced here, and it is readily apparent that claim 20 is supported by the same paragraphs of the specification noted in conjunction with the claim chart of claim 19 above.

"Claim 20. (New) A method for accelerating recovery of humans experiencing extreme physical stress to near functional capacity comprising feeding a human experiencing extreme physical stress near physical functional capacity from about 50mg to about 200 mg of L-theanine mixed in a foodstuff or drink, and then, following consumption of the mixed foodstuff or drink, resting the extremely physically stressed human, for a period of 30 minutes to obtain complete regeneration of the human to an unstressed physical condition."

5. Applicant had an absolute right to replace claims 1 to 18 with more limited claims 19 to 25, as long as the limitations are supported by the specification, because applicant was responding to a non-Final Action, and merely presenting more limited claims to the same invention claimed more broadly by claims 1 to 18. In support of the new claims, an evidential Declaration Under Rule 1.132 was submitted together with corroborating documentation showing the actual reduction to practice of the invention claimed in claims 19 to 25, as well as, clinical data proving the efficacy of the invention and unexpected results.
6. The Examiner, in the Office communication of June 20, 2007 was plain wrong in stating at the beginning of the 2nd paragraph of the Office communication that "All previous claims were drawn to methods for acceleration of a physiological recovery process of a body of a user after physical and/or mental stressing comprising administering L-theanine." The implication being that if applicant were to limit the claimed invention to only physical stressing, that would be a new distinct non-elected invention. In fact, claim 1, as noted above was not so limited and was directed to "Method for acceleration of a physiological recovery process of a body of a user after a physical exertion". Claim 11 was directed to physical *and/or* (emphasis added) mental stressing. As the claim recited "and/or", Applicant has a right to drop "mental stressing" from the claims, and point the invention solely at physical stressing or exertion (claim 1). If the Examiner position is *reductio ad absurdum*, then any limitation of a claim would automatically produce a "non-elected" invention, because the added limitation was not present in the former claim.

Reconsideration and withdrawal of the Office communication and the holding of non-responsiveness of the amendment filed April 13, 2007 is earnestly solicited. Further, favorable consideration of new claims 19 to 25, fully supported by the disclosure of the specification is also earnestly solicited, in view of the evidentiary Declaration Under Rule 1.132 with corroborating documentation filed with the amendment of April 13, 2007, proving the novelty, utility, efficacy and unexpected results of the present invention, as now claimed in claims 19 to 25. The new claims 19 to 25 are fully supported by the specification, directed to same invention continuously being claimed in this application from its inception and are in full compliance with the requirements of 35 USC § 112, first and second paragraphs.

In light of the foregoing remarks, this application should be in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding the application, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned; the application has been pending since 2003.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time, time sufficient, to effect a timely response, and shortages in this or other fees, be charged, or any overpayment in fees be credited, to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 7390-X03-020).

Respectfully submitted,

A handwritten signature in cursive script that reads "Martin Fleit".

Martin Fleit, Reg. #16,900

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